No. 89-243

IN THE

# Supreme Court of the United States

OCTOBER TERM, 1989

**ELI LILLY AND COMPANY,**

*Petitioner,*

v.

**MEDTRONIC, INC.,**

*Respondent.*

**On Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit**

## BRIEF ON BEHALF OF COOK GROUP INCORPORATED AS AMICUS CURIAE IN SUPPORT OF RESPONDENT MEDTRONIC, INC.

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## INTEREST OF AMICUS CURIAE

Cook Group Incorporated is the parent and holding company for over thirty independent corporations (hereinafter collectively "Cook") involved in all aspects of the development, manufacture and marketing of medical devices. For over 26 years, Cook companies have been dedicated to the medical device business and to improving public health

and well being. Cook submits its brief in support of the Respondent Medtronic, Inc. ("Medtronic") in seeking affirmance of the decision below. Consent in writing was sought and obtained both from Medtronic and from the Petitioner Eli Lilly and Company ("Lilly") to the filing of Cook's brief. Copies of these consents are on file with the Clerk of this Court.

In explanation of its background and interest, Cook began as the dream of William A. Cook and his wife Gayle in 1963 to service the emerging field of percutaneous entry catheterization as a diagnostic means in lieu of the popular method of "exploratory surgery." Cook Incorporated was formed as a medical device manufacturer, and remains a major component in the Cook family of companies. Working principally with radiologists and cardiologists through the early years, it became apparent to Cook that other medical disciplines could also benefit from this technology and approach. Over time, Cook companies expanded into the fields of urology, gastroenterology, critical care and cardiac pacing. Cook companies were also added in the fields of plastic extrusions and moldings, stainless steel cannula manufacture and many support services.

Through this effort, Cook has emerged as a multinational group of independent, privately-owned companies intricately involved in the medical device business. Along the way, Cook spearheaded the work *inter alia* of Dr. Charles Dotter (once nominated for the Nobel prize in medicine for his work in this area) and funded many millions of dollars in private and public research including the recent establishment of The Charles Dotter Institute of Diagnostic and Interventional Radiology as an interdisciplinary medical facility at the University of Oregon. Cook has also been an active participant and supporter of patent systems, both U.S. and foreign, and has benefited both as



a patent owner and by learning from and improving upon the patented technology of others. As a result, Cook is a recognized leader in the creation and growth of interventional medicine in this Country.

In view of its past history and present status, Cook has a unique perspective from which to address the issues now before this Court. Cook has grown from a small family-run business to a significant medical device manufacturer, paralleling the growth and regulation of the medical industry by the Food and Drug Administration ("FDA"). Cook has a long working knowledge of the FDA, including routine if not daily contact regarding the thousands of devices Cook manufactures and markets. At the same time, Cook has remained independently and privately owned, retaining a family-run atmosphere divorced from shareholder and related pressures. This affords Cook a unique and different perspective on how a manufacturer of medical devices can influence the development of new products to improve the public health.

While Cook has monitored the progress of this case in the lower courts, Cook has now come forward for two important reasons: The first is to offer this Court Cook's unique perspective as suggested above. The second is to prevent this Court being misled by any suggestion of Lilly and its amici that all medical manufacturers abhor and detest the decision below. Quite the contrary, Cook is not only undisturbed by it, but applauds the Federal Circuit's decision. That decision does not curtail innovation of medical devices in this Country, but spurs on competition and earlier development and marketing of improvement products for the public well being. That decision does not rob the reward and hence the incentive from creativity, but returns opportunity to small companies often more innovative but unable to compete in off-shore clinical testing and

the like. That decision does not erode patent protection, but puts it back on course lessening any undue extension of the patent "monopoly" through increased FDA complexity and other regulation that often require years of testing and millions of dollars in investment. This dilemma, often referred to as the "regulatory patent", has worsened in recent years as large and small manufacturers alike have been increasingly hurt to the ultimate detriment of the public. *Roche v. Bolar* aggravated this situation, but Congress in enacting 35 U.S.C. § 271(e)(1) and the Federal Circuit's decision below are significant strides in the right direction.

Contrary to the views of Lilly and its amici, Cook supports Medtronic in requesting this Court to affirm the Federal Circuit's decision. In support of this position, Cook submits two alternative bases at law and persuasive policy considerations discussed below.

## SUMMARY OF ARGUMENT

As its premise, Cook submits that testing of medical devices to meet FDA requirements is a permissible experimental use and therefore not an infringement of patents covering such devices. As such, the testing conduct comes within the judicially-created experimental use exception.

If in 1984 the Federal Circuit judicially removed both testing of drugs and testing of medical devices from the ambit of experimental use by its holding in *Roche v. Bolar*, then Congress has replaced both types of testing within the experimental use exception pursuant to its enactment of 35 U.S.C. § 271(e)(1), which was intended by Congress to overrule *Roche*.



If, on the other hand, the Federal Circuit's holding in *Roche* removed only the testing of drugs from the exception, then the testing of medical devices remains within the ambit of the judicially-created experimental use doctrine.

In either case, the testing of medical devices to meet FDA requirements is noninfringing experimental use—whether statutorily created by 35 U.S.C. § 271(e)(1) or judicially created by the experimental use doctrine. The Federal Circuit's decision was therefore correct at law and is supported by policy considerations as discussed below.

## ARGUMENT

### I.

### The Experimental Use Exception Encompasses Conduct Which Does Not Deprive The Patentee Of The Lawful Rewards Of His Invention.

#### A. The Origins of the Experimental Use Exception.

The right of the patentee to exclude others from making, using or selling his patented invention has long been engrafted with the judicially-created exception that an experimental manufacture, use or sale is not an infringement. This exception spawned from language in two opinions authored by Justice Story of this Court. In *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600), arguably in dicta, Justice Story stated that the legislature could never have intended, in enacting the then-existing patent statute, to punish one who manufactured an infringing machine for "philosophical experi-

ments" or "for the purpose of ascertaining the sufficiency of the machine to produce its described effects."

Several months later, Justice Story held in *Sawin v. Guild*, 21 F. Cas. 544 (C.C.D. Mass. 1813) (No. 12,391), that the experimental use exception he had discussed in *Whittemore* with respect to "making" a patented invention also applied to "selling" a patented invention. Just as "making" a patented invention is an infringement only if it deprives the patentee of the lawful rewards of his discovery, so too is "selling" a patented invention an infringement only if it deprives the patentee of the "use and benefit of his patent."[1] *Id.* at 555.

**B. Later Cases Applying the Experimental Use Doctrine.**

As in its inception, the experimental use exception to infringement has continued to be based upon the premise that a qualified manufacture, use or sale does not deprive the patentee of the *lawful* rewards of his patent. Several cases have applied that reasoning to conduct similar to that at issue here, and have found no infringement based

[1] Several commentators have suggested that the experimental use language in *Sawin v. Guild* was also dicta, although nonetheless supporting the doctrine's existence. Israelsen, *Making, Using, and Selling Without Infringing: An Examination of 35 U.S.C. Section 271(e) And The Experimental Use Exception To Patent Infringement*, 16 Am. Intell. Prop. L.A.Q.J. 457, 459 (1989); Bee, *Experimental Use as an Act of Patent Infringement*, 39 J. Pat. Off. Soc'y. 357, 364 (1957). However, in *Sawin* Justice Story was faced with conduct which came squarely within the words of the statute giving the exclusionary right of sale to the patentee. Even though the defendant deputy sheriff had seized the patentee plaintiff's machines under a writ of execution and sold the patented machine pursuant to the writ, Justice Story held the statute could not be interpreted to encompass his conduct. This holding was based, at least alternatively, on the fact that the sheriff had deprived the plaintiff only of material and not of the benefit of his patent.



upon the experimental use doctrine. *Chesterfield v. United States*, 159 F. Supp. 371, 375 (Ct. Cl. 1958) (The court found that the government's use of a cobalt-nickel alloy for "testing and for experimental purposes" was not an infringing use.); *Dugan v. Lear Avia, Inc.*, 55 F. Supp. 223, 229 (S.D.N.Y. 1944), *aff'd on other grounds*, 156 F.2d 29 (2d Cir. 1946) (The court found one direction-finding, position-indicating system noninfringing because Lear built the system experimentally and neither manufactured it for sale, nor sold it.); *Akro Agate Co. v. Master Marble Co.*, 18 F. Supp. 305, 333 (N.D. W. Va. 1937) (The court found Master Marble's use of a patented machine for making glass marbles was not an infringement but rather was experimental testing for a brief period before going into commercial production with a noninfringing machine, the marbles so made having not been commercially sold.)

While other courts have focused on the defendant's present commercial exploitation of the patented invention in refusing to apply the experimental use exception,[2] the

[2] *Compare, Bonsack Machine Co. v. Underwood*, 73 F. 206 (C.C. E.D.N.C. 1896) (contract with 60-day option to purchase infringing machine, *inter alia*, was not experimental use); *Cimiotti Unhairing Co. v. Derboklow*, 87 F. 997 (C.C.E.D.N.Y. 1898) (use of patented machine on customer pelts was not experimental); *Imperial Chemical Industries, PLC v. Henkel Corp.*, 545 F. Supp. 635 (D. Del. 1982) (supplying potential customers with samples of patented compound, *inter alia*, was not experimental use); *Poppenhusen v. New York Gutta Percha Comb Co.*, 19 F. Cas. 1048 (C.C. S.D.N.Y. 1861) (No. 12,279) (placing infringing articles in the market in competition with patent owner was not experimental); *Radio Corp. of America v. Andrea*, 15 F. Supp. 685 (E.D.N.Y. 1936) (quality control testing of commercial production was not experimental use); *Spray Refrigeration Co. v. Sea Spray Fishing, Inc.*, 322 F.2d 34 (9th Cir. 1963) (use of patented method in commercial fishing operation was not experimental); and *United States Mitis Co. v. Carnegie Steel Co.*, 89 F.343 (W.D. Pa. 1898), *aff'd*, 90 F. 829 (C.C.A.Pa. 1898) (use of invention in the course of business and for profit was not experimental).

*Chesterfield, Dugan* and *Akro* cases stand for the proposition that even though the experimenter is in a business related to the patented invention and his activity has a definite view toward some future commercial adaptation or benefit, this is not determinative of infringement without concurrent actions to enter the relevant market or otherwise deprive the patent owner of his lawful rewards during the term of the patent.

## II.

**The Testing And Obtaining Of Government Approval For Medical Devices Does Not Deprive The Patentee Of The Lawful Rewards Of His Invention.**

The patent statute grants to the patentee, his heirs or his assigns, the right to exclude others from making, using or selling the invention throughout the United States for the term of seventeen years. 35 U.S.C. § 154. This grant gives the patentee the "right to be free from competition in the practice of the invention," but only within the narrow and strictly confined limits of the precise terms of the grant. *Mercoid Corp. v. Mid-Continent Investment Co.*, 320 U.S. 661, 665 (1941).

Clearly, Medtronic, Lilly and others who through R&D test and attempt to obtain government approval for future generic medical devices have an intention at some time after the expiration of any patents to commercially use and hopefully profit from what may presently be patented devices or other technology. So too is their intention to improve upon such available devices for the general public health and well being. This future intention to commercially exploit such medical devices at a time when they are part of the public domain in no way deprives the patentee of the *lawful* rewards of his invention.



The patent statute only grants seventeen, not seventeen *plus*, years of protection. The patentee is not entitled to freedom from competition based upon the patent statute after his patent has expired. *Brulotte v. Thys Co.*, 379 U.S. 29, 32-33 (1964) (If the patent exclusivity could be projected after the patent expires, "the free market visualized for the post-expiration period would be subject to monopoly influences that have no proper place there."); *Scott Paper Co. v. Marcalus Mfg. Co.*, 326 U.S. 249, 255-256 (1945) ("[A]ny attempted reservation or continuation in the patentee . . . of the patent monopoly, after the patent expires, whatever the legal device employed, runs counter to the policy and purpose of the patent law."); and *Bonito Boats, Inc. v. Thunder Craft, Inc.*, 489 U.S. ____, 103 L.Ed. 2d 118, 135 (1989) ("It is self-evident that on expiration of a patent the monopoly created by it ceases to exist, and the right to make the thing formerly covered by the patent becomes public property.") Nevertheless, the complexities of FDA and other regulatory requirements for medical devices can lead to this very result.

Congress has stated with respect to bioequivalency testing that such testing and obtaining of government approval does not have an adverse economic impact on the patentee's exclusivity during the 17-year life of his patent. H. R. Rep. No. 854, 98th Cong., 2d Sess. 46, *reprinted in 1984 U.S. Code Cong. & Admin. News* 2647, 2679. "The patent owner retains the right to exclude others from the major commercial marketplace during the life of the patent. Thus the nature of the interference with the rights of the patent holder is not substantial." H. R. Rep. No. 854, 98th Cong., 2d Sess. 8, *reprinted in 1984 U.S. Code Cong. & Admin. News* 2686, 2692. This express reasoning is just as applicable to medical devices as to drugs. Israelsen, *supra*, at 464-65.

## III.

**The Federal Circuit In *Roche* Removed From The Experimental Use Exception All Experiments Conducted With A View To The Adaptation Of The Patented Invention To The Experimenter's Business.**

In *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984), the Federal Circuit examined for the first time the experimental use exception to patent infringement. The Federal Circuit recognized two important truths with respect to experimental use . . . first, that the scope of the term "use" in 35 U.S.C. § 271(a) has never been taken to its utmost scope; and second, that experimental use may be a defense to infringement. *Id.* at 861.

The Federal Circuit interpreted the experimental use exception very narrowly. The holding in *Roche* was that the defendant's use of a drug for testing and investigation related to FDA approval requirements was not an experimental noninfringing use because the use was made with a view to the adaptation of the patented drug to the defendant's business. *Id.* at 863. While outsiders may debate whether the Federal Circuit's removal of *all* such experiments from the ambit of the doctrine was by precedential holding or dicta, the Federal Circuit has itself recognized the breadth of its decision:

> While the claimed subject matter in *Roche* was limited to a drug product, the holding of that case was not so limited. The holding provided an interpretation of the scope of 35 U.S.C. § 271(a) without regard to what particular goods might be involved. Specifically, the court decided that the unlicensed use of a patented invention for testing and investigation, even though strictly related to obtaining FDA approval for a substitute, was an infringement under 35 U.S.C. § 271(a).

*Eli Lilly & Co. v. Medtronic, Inc.*, 872 F.2d 402, 406 (Fed. Cir.), *cert. granted*, 110 S. Ct. 232 (1989).



## IV.

**In Enacting 35 U.S.C. § 271(e)(1), Congress Intended Expressly Or Implicitly To Replace Within The Experimental Use Exception The Conduct Which The Federal Circuit Had Removed In *Roche*.**

The uproar in the medical industry following *Roche* was loud, and Congress' remedy swift. Congress explicitly stated that the provisions of the Bill adding § 271(e)(1) "have the net effect of reversing the holding of the court in *Roche*." H. R. Rep. No. 854, 98th Cong., 2d Sess. 27, *reprinted in 1984 U.S. Code Cong. & Admin. News* 2647, 2711. The Federal Circuit itself recognized that Congress' addition of § 271(e)(1) to the patent statute "overruled *Roche*". *Eli Lilly & Co., supra*, 872 F.2d at 405.

Thus, whether one interprets the holding in *Roche* broadly as did the Federal Circuit or narrowly as do Lilly and its amici, Congress intended to replace within the ambit of the experimental use exception to patent infringement whatever *Roche* by its holding had removed. With this understood, surely it can not be effectively argued that the underlying rationale of *Roche* in narrowly interpreting the experimental use doctrine has any remaining validity.

Extending this analysis, the testing of medical devices to secure FDA approval falls within the same umbrella justifying experimental use protection. If such testing was expressly removed from the experimental use doctrine by

the Eederal Circuit's holding in *Roche*, it was replaced by Congress' enactment of 35 U.S.C. § 271(e)(1). If such testing was not removed by the holding in *Roche*, then it remains excused under the judicially-created experimental use doctrine and the discredited rationale in *Roche* should not be applied to overturn this result.

## V.

**Persuasive Policy Considerations Support This Court's Affirmance Of The Federal Circuit's Decision.**

Thus far, Cook has addressed alternative bases at law to support this Court's affirmance of the Federal Circuit's decision either through interpretation of Congress' enactment of § 271(e)(1) or through interpretation of the judicially-created experimental use exception. There remains the need to comment on considerations of policy proposed by Lilly and its amici which Cook finds ill-conceived and possibly misleading of this Court.

For example, its detractors challenge the Federal Circuit's decision as significantly eroding and devaluing patent protection in medical devices. Certainly, this is not the case. Statutory and judicial safeguards are well in place to assure that preexpiration uses of a patented device are "experimental" and "... solely for uses reasonably related to the development and submission of information under a Federal law ...." 35 U.S.C. § 271(e)(1). It is wrong to assume the courts or the FDA or other regulatory agencies will fail in their duty to police potential abuses.

Moreover, equally-corrupt abuses existed in the past, and yet today, which are ameliorated by the decision below. FDA and other government regulations in the medical area have become increasingly complex over the years



resulting in *de facto* extensions of the patent term in what is often referred to as the "regulatory patent." The Federal Circuit's decision lessens the chance of such expansions of the patent "monopoly" occurring in the future to administratively create any superior class of patent owners.

Its detractors also challenge the Federal Circuit's decision as providing a significant adverse effect on medical device innovation and resulting disincentives for technology development and investment which otherwise benefit the public health and well being. Quite the contrary is true. A more expansive interpretation of the § 271(e)(1) exemption or the experimental use exception in fact opens up opportunities for the public and private sector to more rapidly and effectively assimilate new advancements in medical devices. Certainly, the advantages of independent access and verification by one's peers and the availability of prior invention to spur on future innovation are accepted scientific facts.

In the real world, as a patent nears its term, competitors assess the market for potential generic or substitute applications. So too do these competitors, and the patentee, assess the potential for improvement or spin-off utility of a patent throughout its life. If a new or generic medical device requires clinical testing, the manufacturer must not only reverse engineer the "clone" or its improvement, but in many instances must also obtain FDA marketing approval which at times can delay the introduction of such new or competing products for years. It could not have been the Framer's intent in our Constitution or Congress' intent in first enacting a patent statute or now with § 271 that all progress requiring use of a patented discovery for investigation or experiment should completely halt for the 17-year limited exclusivity

provided by law. On the contrary, the Constitutional mandate to "promote the progress of . . . the useful arts . . ." and statutory prescriptions ensuring early disclosure of inventions, including their adequate enablement and best modes, and acknowledging the availability of improvement patents certainly speak against any such conclusion. Israelsen, *supra*, at 472.

Yet another misconception of these detractors is that the Federal Circuit's decision somehow unfairly prejudices the small manufacturer who does constitute a major segment of the medical device industry. Cook submits that the facts show otherwise. A review of recent acquisitions in this industry will demonstrate that small company innovation is still alive in this Country. This is true even with the disadvantage to small industry of the *Roche* holding and its rationale. Indicative of the current malaise is that major corporations prefer acquisition to internal development in many instances. Where this is not available, the ability of major industry to afford protracted regulatory procedures and off-shore clinical testing has severely prejudiced the small manufacturer in this industry.[3] The Federal Circuit's decision brings small industry more at par with its larger relative. Under the decision below, the small manufacturer will now be encouraged to invest in verifying and improving upon its own innovation and that of others subject to the safeguards of § 271(e)(1) and the experimental use doctrine. As a result, the public

[3] The public policy considerations in this Country against forcing or encouraging research and development technology overseas is above reproach. *See* Israelsen, *supra*, at 475, note 86, *citing, e.g.*, Cohen C., *Reagan Proposes a Bold Initiative*, Electronics 33 (August 6, 1987) (related to superconductors, in particular). Nevertheless, Lilly in its Petitioner's Brief to this Court at page 31, note 21, encourages Medtronic in this option.



will benefit from the encouragement of more rapid innovation and adaptation of existing discoveries.

Still another challenge to the decision below questions the Federal Circuit's special expertise in this area. In view of its unique history, however, the Federal Circuit is in fact the most appropriate forum short of this Court to have interpreted and applied patent policy in this Country in deciding the issues at hand.

## CONCLUSION

As addressed above, support at law for the Federal Circuit's decision is found either in the § 271(e)(1) enactment or in the experimental use exception to patent infringement which was freed up by Congress' overruling of the earlier holding in *Roche*. More importantly, persuasive policy considerations support the Federal Circuit's decision and this Court's affirmance thereof. Accordingly, there being no clear error of law or public policy in the Federal Circuit's decision, it is requested that this Court decline the Petitioner's invitation to reverse and that this Court affirm the decision below in its entirety.

Respectfully submitted,

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